

November 4, 2016



# **Aurinia Reports Third Quarter 2016 Financial Results and Operational Highlights**

***AURA first global clinical trial in lupus nephritis that meets primary and all secondary endpoints***

***AURION 24-week results support the use of voclosporin for the treatment of lupus nephritis***

***Successful completion of EOP2 meeting with FDA***

VICTORIA, British Columbia--(BUSINESS WIRE)-- Aurinia Pharmaceuticals Inc. (NASDAQ:AUPH)(TSX:AUP) ("Aurinia" or the "Company") has released its financial results for the third quarter ended September 30, 2016. Amounts, unless specified otherwise, are expressed in U.S. dollars.

Aurinia plans to initiate a single, Phase 3 clinical trial (AURORA) whose design is consistent with that of the ongoing AURA clinical trial. The totality of data from both trials will serve as the basis for a New Drug Application (NDA) submission following completion of the Phase 3 trial, and the Company is focusing its efforts on finalizing the study protocol and regulatory submissions in parallel with site selection, making the necessary investments now to ensure the team has the tools to execute a successful clinical trial.

"We have made exceptional progress over the last few months announcing the first global clinical trial in LN to meet its primary and all secondary endpoints," said Charles Rowland, CEO of Aurinia Pharmaceuticals. "Additionally, the recent selection of the AURA Phase 2b results for late-breaking presentations by the American College of Rheumatology (ACR) and American Society of Nephrology (ASN) is a testament to the hard work executed by our world-class clinical team. We look forward to advancing voclosporin into Phase 3 for the treatment of LN and pursuing our goal of helping patients living with this devastating disease."

## **Operational Highlights**

### **FDA End of Phase 2 Meeting Update**

On November 2, 2016, the Company announced its plans for a single Phase 3 clinical trial for voclosporin in the treatment of lupus nephritis (LN). Pursuant to its recent End of Phase 2 meeting with the U.S. Food & Drug Administration (FDA) Division of Pulmonary, Allergy and Rheumatology Products, Aurinia believes this Phase 3 clinical trial whose design is consistent with the ongoing AURA study, will support a New Drug Application (NDA) submission. Preparations are underway for the Phase 3 AURORA trial, which is planned to

initiate in Q2 2017.

## AURA Phase 2b Clinical Trial Update

On August 15, 2016, the Company announced positive top-line results for the AURA clinical trial. The trial met its primary endpoint, with voclosporin 23.7mg BID showing a statistically significant improvement ( $p=.045$ ) in complete remission (CR). Each arm of the trial included the current standard of care of mycophenolate mofetil (MMF) as background therapy and a forced steroid taper to 5 mg/day by week 8 and 2.5 mg by week 16. No unexpected safety signals were observed and voclosporin was shown to be well tolerated.

On September 30, 2016, the Company announced that in addition to achieving its primary endpoint, voclosporin also met all 24-week pre-specified secondary endpoints in the Phase 2b AURA clinical trial for LN.

Pre-specified Secondary Endpoint	Control	Low Dose VCS (23.7mg BID)	High Dose VCS (39.5mg BID)
<b>Time to Complete Remission (TTCR)</b> [median]	Not achieved	19.7 weeks <b><math>p&lt;.001</math></b>	23.4 weeks <b><math>p=.001</math></b>
<b>Partial Remission</b> (as measured by UPCR reduction of $\geq 50\%$ from baseline)	49%	70% <b><math>p=.007</math></b>	66% <b><math>p=.024</math></b>
<b>Time to Partial Remission (TTPR)</b> [median]	6.6 weeks	4.1 weeks <b><math>p=.002</math></b>	4.4 weeks <b><math>p=.003</math></b>
<b>SLEDAI Reduction</b>	-4.5	-6.3 <b><math>p=.003</math></b>	-7.1 <b><math>p=.003</math></b>
<b>Reduction in UPCR</b>	-2.216 mg/mg	-3.769 mg/mg <b><math>p&lt;.001</math></b>	-2.792 mg/mg <b><math>p=.006</math></b>

## AURION Clinical Trial Update

On October 6, 2016 the Company announced results from all 10 patients at 24 weeks of the ongoing open-label AURION clinical trial. In this clinical trial, 70% (7/10) patients achieved complete remission (CR) at 24 weeks as measured by a urinary protein creatinine ratio (UPCR) of  $\leq 0.5$ mg/mg, eGFR within 20% of baseline and concomitant steroid dose of  $<5$ mg/day. Of the 10 patients that achieved a reduction of UPCR of  $\geq 25\%$  at 8 weeks, 80% were responders ( $\geq 50\%$  reduction in UPCR over baseline) at 24 weeks and 70% were in CR at 24 weeks. In addition, C3, C4, anti-dsDNA all continued to normalize to 24 weeks. Voclosporin was well-tolerated with no unexpected safety signals observed.

## Initiation of Phase 1 Japanese Study

The Company has initiated discussions with the Japanese regulatory authorities to understand their perspective on gaining approval for voclosporin in their jurisdiction. The Company's goal will be to obtain their acceptance of the same development plan as reviewed with FDA. To that end, the Company, in October of 2016, has initiated a Phase 1 study in healthy Japanese volunteers to permit Japanese sites to potentially participate in the

Phase 3 trial.

**The Company expects the following milestones and events for the rest of 2016 and first half of 2017:**

- Late breaking presentations at the American College of Rheumatology (ACR) and the American Society of Nephrology (ASN);
- Meetings with European Medicines Agency (EMA) and Pharmaceutical & Medical Devices Agency, Japan (PMDA);
- AURA 48-week secondary endpoint results;
- AURION 48-week results;
- Initiation of Phase 3 program.

**At the Market (ATM) Facility**

On July 22, 2016 the Company entered into a Controlled Equity Offering Sales Agreement with Cantor Fitzgerald & Co. (“Cantor Fitzgerald”) pursuant to which the Company was able to, from time to time, sell common shares through at-the-market (“ATM”) offerings with Cantor Fitzgerald acting as sales agent.

As of October 3, 2016, sales pursuant to the ATM were concluded. The Company issued 3.3 million common shares, receiving gross proceeds of \$8 million (\$6.1 million in the third quarter of 2016 and \$1.9 million subsequent to the quarter end) which was the maximum allowable pursuant to the limit imposed by Toronto Stock Exchange rules.

**Financial Results for the Third Quarter Ended September 30, 2016**

The Company had cash, cash equivalents and short term investments of \$15.4 million at September 30, 2016 compared to \$12.1 million at June 30, 2016 and \$15.8 million at December 31, 2015. Net cash used in operating activities was \$5.0 million for the third quarter ended September 30, 2016. The Company generated \$7.4 million from financing activities during the quarter resulting from net proceeds of \$5.7 million received from the issue of common shares pursuant to the ATM facility and \$1.7 million from warrant and option exercises in the third quarter of 2016.

For the third quarter ended September 30, 2016, the Company reported a consolidated net loss of \$7.4 million or \$0.21 per common share, as compared to a consolidated net loss of \$5.2 million or \$0.16 per common share for the same period in 2015. The increase in the reported consolidated net loss was primarily attributable to recording a non-cash loss of \$951,000 on the quarterly fair value revaluation of the derivative warrant liability compared to a gain of \$1.2 million to the same period in 2015.

For the nine months ended September 30, 2016, the consolidated net loss was \$15.0 million or \$0.44 per common share compared to a consolidated net loss of \$14.5 million or \$0.45 per common share for the comparable period in 2015.

Research and development expenses decreased to \$3.3 million for the three months ended September 30, 2016, compared to \$4.7 million for the three months ended September 30,

2015. The Company incurred net research and development expenditures of \$9.1 million for the nine months ended September 30, 2016, as compared to \$12.3 million for the same period in 2015. The decrease is primarily the result of a reduction of ongoing costs related to the active patient portion of the AURA clinical trial as patients complete the trial.

Corporate, administration and business development expenses increased to \$1.7 million for the three months ended September 30, 2016, compared to \$1.4 million for the same period in 2015. The Company incurred corporate, administration and business development expenses of \$4.7 million for the nine months ended September 30, 2016 compared to \$4.7 million for the same period in 2015.

The unaudited interim condensed consolidated financial statements and the MD&A for the third quarter ended September 30, 2016 are accessible on Aurinia's website at [www.auriniapharma.com](http://www.auriniapharma.com) or on SEDAR at [www.sedar.com](http://www.sedar.com) or on EDGAR at [www.sec.gov/edgar](http://www.sec.gov/edgar).

### ***About Aurinia***

Aurinia is a clinical stage biopharmaceutical company focused on developing and commercializing therapies to treat targeted patient populations that are suffering from serious diseases with a high unmet medical need. The Company is currently developing voclosporin, an investigational drug, for the treatment of lupus nephritis (LN). The Company is headquartered in Victoria, BC, Canada and focuses its development efforts globally.

### ***About AURA:***

The AURA–LV clinical trial (Aurinia Urine protein Reduction in Active Lupus with voclosporin) is a 48-week clinical trial comparing the efficacy of two doses of voclosporin added to current standard of care of MMF against standard of care with placebo in achieving complete remission (CR) in patients with active LN. All arms also received low doses of corticosteroids as background therapy. 265 patients were enrolled at centers in 20 countries worldwide. On entry to the trial, patients were required to have a diagnosis of LN according to established diagnostic criteria (American College of Rheumatology) and clinical and biopsy features indicative of highly active nephritis. The 24-week primary and secondary endpoints were released in Q3 2016 with 48-week secondary endpoint results to be announced in Q1 2017.

### ***About AURION:***

The AURION clinical trial or “Aurinia Early Urinary Protein Reduction Predicts Response Study” is an open-label, exploratory study being conducted in two sites in Malaysia to assess the short term predictors of response using voclosporin (23.7mg) in combination with mycophenolate mofetil and oral corticosteroids in patients with active lupus nephritis. This study will examine biomarkers of disease activity at 8 weeks and their ability to predict response at 24 and 48 weeks.

### ***About AURORA:***

The AURORA study is a 52-week global double-blind placebo controlled phase 3 study that will compare the efficacy of one dose of voclosporin (23.7mg BID) or placebo added to

current standard of care of mycophenolate mofetil (MMF, also known as CellCept®) in achieving renal response (formerly referred to as complete remission) in patients with active LN. Both arms will also receive low doses of corticosteroids as part of background therapy after a stringent taper.

### ***Forward-Looking Statements***

This press release contains forward-looking statements, including statements around Aurinia's analysis, assessment and conclusions around the future development and commercial potential of voclosporin; the benefits of FDA fast track designation and the timing of future clinical trials.;summary statements relating to results of the past voclosporin trials; the timing of commencement and completion of clinical trials; the timing of the Company's anticipated milestones for 2016 and 2017; and plans and objectives of management.

It is possible that such results or conclusions may change based on further analyses of these data, Words such as "plans," "intends," "may," "will," "believe," and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon Aurinia's current expectations. Forward-looking statements involve risks and uncertainties. Aurinia's actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, the risk that Aurinia's analyses, assessment and conclusions of the results of the future development and commercial potential of voclosporin set forth in this release may change based on further analyses of such data, and the risk that Aurinia's clinical studies for voclosporin may not lead to regulatory approval. These and other risk factors are discussed under "Risk Factors" and elsewhere in Aurinia's Annual Information Form for the year ended December 31, 2015 filed with Canadian securities authorities and available at [www.sedar.com](http://www.sedar.com) and on Form 40-F with the U.S. Securities Exchange Commission and available at [www.sec.gov](http://www.sec.gov), each as updated by subsequent filings, including filings on Form 6-K. Aurinia expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in Aurinia's expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

Such forward-looking statements involve known and unknown risks, uncertainties, and other factors that may cause the Company's actual results, performance, or achievements to differ materially from any further results, performance or achievements expressed or implied by such forward-looking statements. Important factors that could cause such differences include, among other things, the following:

- the need for additional capital to fund the Company's development programs and the effect of capital market conditions and other factors on capital availability;
- difficulties, delays, or failures the Company may experience in the conduct of and reporting of results of its clinical trials for voclosporin, and in particular its current AURA clinical trial;
- difficulties, delays or failures in obtaining regulatory approvals for the initiation of clinical trials;
- difficulties the Company may experience in completing the development and

commercialization of voclosporin;

Although the Company believes that the expectations reflected in the forward-looking statements are reasonable, the Company cannot guarantee future results, levels of activity, performance or achievements. These forward-looking statements are made as of the date hereof.

*We seek Safe Harbor.*

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